K043195

SECTION 2.

MAR 7 - 2005

A. 510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Neoss Ltd summary for the ***Neo Implant System.***

SUBMITTER'S NAME: Neoss Ltd
ADDRESS: Windsor House
Cornwall Road
Harrogate, HG1 2PW, UK
CONTACT PERSON: Fredrik Engman
TELEPHONE NUMBER: +44 (0) 1423 817733 , +46 (0)709 792 892
FAX NUMBER: +44(0) 1423 817744
E-MAIL fredrik@neossimplant.com

DATE OF SUBMISSION: Nov 5, 2004

1. Identification of device

Classification name: Implant endosseous root-form
Proprietary Name: Neo Implant System
Common Name: Dental implant, Dental abutment, Abutment screw
Round bur, Twist drill, Countersink and Screwtap
Classification Status: Class II per regulations 872.3640
Product Codes: DZE

2. Equivalent devices

Neoss Ltd believes the ***Neo Implant*** is substantially equivalent to the following implant fixtures including temporary parts (cover screw and healing abutment);

- Astra Tech Implants Dental System- Immediate function, nr K041492

and the following ***abutments***:

- Astra Tech Implants- Dental system, nr K931767 (Neo Titanium, Neo gold, ball, bar, abutment screw)

- Astra Tech implant- Dental System Additional components, nr K974738. (Ti prepable abutments).

Neoss Ltd also believes the ***bone cutting instruments*** are substantially equivalent to the following implant fixtures;

- 3i single use, disposable drills, taps, burs etc.- nr K962014 (non-sterile reusable components)

K043795

3. Description of the Device

Implant fixture:
The *Neo implant* is a threaded, internal abutment connection, root-form titanium dental implant. The Neo implant assortment consists of a number of implants with a diameter of Ø3,5 to Ø5,5 mm and lengths between 7,0 - 19.0 mm having the same internal abutment dimension independent of implant diameter. The internal connection being equiped with interlocking elements for an insertion tool and the non-rotational locking of the abutment. Supplied sterile.

Temporary part related to the fixture - Cover screw;
Made in titanium for implantation. Supplied sterile.

Temporary part related to the fixture - Healing abutment;
Made in titanium or PEEK for implantation. Supplied sterile.

Abutments;
The Neo Abutment system is a set of modifiable gold alloy or commercially pure titanium abutments (Neolink), which are secured directly to the implant using an abutment screw. For easy wax-up a set of pre-shaped plastic copings can be used to fit to the abutment. Supplied non-sterile.

Prepable Ti abutments; Prepable titanium abutments of straight or angle (20 degrees or less) design made to be adjusted by clinician or dental technician. Crown or bridge cemented on prepped abutment. Supplied non-sterile.

Bar abutment; straight titanium or gold abutment cylinder to which a bar can be bonded (i.e welded or soldered) or cast on to. Supplied non-sterile.

Ball abutment; conventional design (ball head diameter 2,25 mm) used with standard attachments. Supplied non-sterile.

Abutment screw made in gold alloy or titanium. Screw driver connection compatible with screwdrivers supplied by Neoss. Supplied non-sterile.

Round bur;
The round bur with diameter Ø1,8-2 with is ISO 1797-1 hand piece connection and shaft.

Twist drills;
Two flute twist drill with ISO 1797-1 hand piece connection and shaft. Depth marking corresponding to the implant lengths in the Neoss implant system, hence 7, 9, 11, 13, 15 and 17. Diameter from Ø2,2 to Ø5,1 in appropriate steps to match the Neoss implants.

Screwtap:
Screwtap for the different implant diameters existing in the Neo Implant system (Ø3,5 to Ø5,5) with ISO 1797-1 hand piece connection and shaft.

Countersink;
Countersink for the different implant diameters existing in the Neo Implant system (Ø3,5 to Ø5,5) with ISO 1797-1 hand piece connection and shaft. The tool has a centring tap in relation to the prepared hole.

Material of bone cutting instruments is medical grade stainless steel currently being used for similar components.

4. Intended use

The *Neo Implant* is intended for surgical placement into the bone of upper /lower jaw arches as a permanent anchorage for prosthetic devices, which can restore chewing function, speech and aesthetic appearance. This is accomplished using a single-stage and two-stage surgical procedure and cement or screw retained restorations.
The Neo Implants - Neo Implant System are intended for immediate placement and function on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

The Neo Abutments includes a set of components that are intended to function on Neo implants or compatible external hex, Replace Select implants and Straumann implants, as a base prosthetic construction.

Surgical drills, screwtaps, countersinks or burs are used in dental, oral/maxiofacial surgery for preparing the bone (osteotomy), to receive Neo implant(s) for restorative reconstruction.

5. Technological characteristics, comparison to predicate device.

Substantial equivalence of the ***Neo Implant System*** is based on design similarities between the predicative device and the devices in this application, since the devices are very similar in terms of material, size and basic design.

Like the predicate devices, the ***bone cutting instruments are*** intended to prepare the surgical site and the technique is identical to predicative devices in relation to handpiece connection and rotational speed. The material is stainless steel with machined electro polished surface with laser depth and type marking. The basic design is the same with twist drill design for the drills, countersink with centring tap and a screwtap with adjusted thread profile in relation to the Neo Implants.

6. Discussion of performance testing.

Mechanical testing requested for Screw-type Endosseous Implants are described in the Guideline "Information Necessary for Pre Market Notification Submission for Screw-Type Endosseous Implants", dated December 9, 1996.

Neo implant and abutment designs are within the scope of the Guideline "Information Necessary for Pre Market Notification Submission for Screw-Type Endosseous Implants", dated December 9, 1996, in terms of material, dimensions, and intended use why we have come to the conclusion that further testing will not race new issues of safety and efficacy.

K043175

Neo bone cutting instruments, are in terms of design, material, dimensions, and intended us in all relevant aspect identical to predicative devices why we have come to the conclusion that further testing will not race new issues of safety and efficacy.

Please see section 5. Part B Performance Testing.

7. Conclusion

Based on comparison, the Neo Implants System including bone cutting instruments, from Neoss Ltd, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 - 2005

NEOSS Limited
C/O Dr. Russell P. Pagano
Vice President
M Squared Associates, Incorporated
719 A Street, NE
Washington, DC 20002

Re: K043195
Trade/Device Name: Neo Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: February 24, 2005
Received: February 28, 2005

Dear Dr. Pagano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number K043195

Device Name: ***Neo Implant System***

Indications for Use:

The Neo Implants - Neo Implant System are for single-stage and two-stage surgical procedures and cement or screw retained restorations.
The Neo Implants - Neo Implant System are intended for immediate placement and function on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K043195